

Docket No. JAB-1690

REMARKS/ARGUMENTS

Claims pending are 1-10, 12, 14, 17 and 18. Claims 11, 13, 15 and 16 were previously cancelled by Preliminary Amendment. The present amendment amends claims 1 and 18 and cancels claims 3, 7 and 8. Claims pending after entry of this amendment are 1- 2, 4-6, 9-10, 14 and 17-18.

Applicants' attorney notes that the Office Action of January 12, 2006 rejected several cancelled claims and rejected several claims for having multiple dependency. The previously submitted Preliminary Amendment addressed many of these issues and is of record in PAJR. Additionally, Applicants' attorney respectfully requests the recalculation and refund of any fees charged for multiple dependent claims in view of the previous amendments to claims 4, 5, 6, 7, 8, 9, 10, 12, 14 and 17.

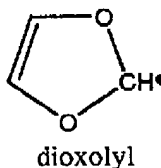
Claims 3, 7 and 8 have been canceled without prejudice or disclaimer of the subject matter thereof. The amendments canceling Claims 3, 7 and 8 are being made solely to advance the prosecution of the instant application and are not in any way to be construed as an admission that the canceled material is unpatentable. Thus, Applicants reserve the right to pursue coverage of the canceled material by filing a continuation or a divisional application at an appropriate time in the future.

Claims 1 and 18 have been amended. No new matter has been added. Accordingly, entry and consideration of these amendments is requested.

The rejection of claims 1-18 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been reviewed. However, Applicants' attorney respectfully request the reconsideration and withdrawal of these rejections in view of the following comments and the above amendments to the claims.

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1. Without conceding the correctness of the rejection and solely to advance the prosecution of the instant application, oxo has been deleted. Applicants reserve the right to present such subject matter in subsequently filed applications.
2. R<sup>3</sup> in claim 1 has been amended to recite the definition from claim 3. Applicants reserve the right to present such subject matter in subsequently filed applications.
3. Claim 7 has been cancelled without prejudice. Applicants reserve the right to present such subject matter in subsequently filed applications.
4. Claim 8 has been cancelled without prejudice. Applicants reserve the right to present such subject matter in subsequently filed applications.
5. Without conceding the correctness of the rejection and solely to advance the prosecution of the instant application, dioxyl has been deleted from claim 1 as a monovalent "Het" ring. Applicants reserve the right to present such subject matter in subsequently filed applications.
6. Contrary to the assertion in the previous Office Action dioxyl is a monovalent "Het" ring. When this term is entered into ChemDraw the following formula is provided:



Applicants' attorney respectfully submits that this is a monovalent "Het" and, therefore requests reconsideration and withdrawal of this rejection.

The rejection of claim 8 under 37 CFR 1.75(c) as being improperly dependent is submitted to be moot in view of the cancellation of claim 8. Accordingly, applicants' attorney respectfully request the withdrawal of this rejection.

The rejection of claims 9-11, 14, and 18 under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot refer back to different sets of claims to different features has been reviewed. Applicants' attorney respectfully submit that this rejection is

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improper. This rejection does not appear to consider applicants Preliminary Amendment submitted on October 1, 2004. Applicants' attorney respectfully submits that claim 11 has been cancelled and claims 9, 10, 14 and 18 are not multiple dependent claims. Applicants' attorney respectfully requests the withdrawal of this rejection.

The rejection of claims 11 and 13-16 under 35 U.S.C. §101 because the claimed invention is directed to a non-statutory subject matter has been reviewed. However in view of the previously submitted Preliminary Amendment, Applicants' attorney respectfully submits that this rejection is improper. Claims 11, 13, and 15-16 were previously cancelled. Claim 14 was previously amended to comport with U.S. claim requirements and converted to a "method" claim. Accordingly, applicants' attorney respectfully submits that claim 14 complies with the requirements of 35 U.S.C. §101.

The rejection of claims 1-5, and 7-18 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement has been reviewed. However, Applicants attorney respectfully submits that a *prima facie* case of non-enablement has not been established or has been rebutted in view of the following comments.

1. Applicants would remind the Examiner that the Applicants' representations in their specification as to the manner of making and using the invention sought to the patent must be taken as in compliance with the first paragraph of 35 U.S.C. §112, unless there is objective evidence or scientifically based reasoning inconsistent with the specification. See In re Marzocchi and Horton, 169 U.S.P.Q. 367 (C.C.P.A. 1971). It is the Patent Offices burden to present this evidence that there is some reason to dispute the enablement provided in the specification. Unsupported speculation or conjecture on that the invention "might not work" will not support a rejection based on 35 U.S.C. §112, first paragraph.

With regard to the starting sources for the tetracyclic rings resulting from the joining of  $R^1/R^2$ , the application describes schemes to make the compounds on page 22, line 13 et seq. Scheme 1 being on page 26 shows how to make the compound where X is  $CH_3$ . Finally, one of

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ordinary skill in art would be able to substitute an SH group for the OH group in the scheme on page 22, line 3 et seq. Thus, applicants' attorney respectfully submits that how to make the present invention is fully enabled. Accordingly, Applicants respectfully submit that the rejection of the specification and claims under 35 U.S.C. §112 is in error. Therefore, Applicants respectfully request the rejection of claims 1-5, and 7-18 under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

2. MPEP §2164.01 states that the "analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention." See August 2005 edition MPEP. Applicants' attorney respectfully submits that the present specification both teaches how to make the claimed invention and how to use the claimed invention in sufficient detail such that one of ordinary skill in the art could both make and use the claimed invention. The specification on pages 18-26 and in the examples describes how to make the claimed invention. The specification on pages 12-17 describes how to use the claimed invention. It is the Patent Offices burden to present this evidence that there is some reason to dispute the enablement provided in the specification. Unsupported speculation or conjecture on that the invention "might not work" will not support a rejection based on 35 U.S.C. §112, first paragraph. See In re Marzocchi and Horton, 169 U.S.P.Q. 367 (C.C.P.A. 1971). Applicants respectfully disagree with the assertion that there is no reasonable basis for assuming compounds made by varying the choice of X and including heteroaryls for R<sup>10</sup>/R<sup>11</sup> are not enabled. This is mere unsupported speculation or conjecture.

The test for whether the present invention will require undue experimentation is set forth in Wands. There are eight (8) Wands factors to be evaluated to make a determination related to undue experimentation:

1. Breadth of the Claims:
2. Amount of direction or guidance presented:
3. Presence of Working Examples:

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4. The Nature of the Invention:
5. State of the Prior Art:
6. Level of Ordinary Skill:
7. Predictability of the art:
8. Quantity of Experimentation needed relative to the disclosure:

MPEP §2164.01(a) states with regards to a rejection based on the Wands' test that "The Examiner's analysis must consider all evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole." Applicants' attorney respectfully submits that the rejection of January 12, 2006 did not include an analysis of all 8 Wands factors. Rather the analysis included a consideration of only 5 of the factors. The level of ordinary skill in the art, nature of the invention, and quantity of experimentation needed relative to the disclosure were not considered. A consideration of all the evidence related to each factor must be conducted. Consequently, a *prima facie* case of nonenablement has not been made. Accordingly, applicants' attorney submits that the rejection of claims 1-5, and 7-18 under 35 U.S.C. §112, first paragraph, is improper and must be withdrawn.

Applicants' attorney also notes that the other compounds have been made in this field such as are described in WO 02066484 (applicants do not admit that such application is prior art). However, applicants' attorney respectfully would point out that contrary to the assertion in the Office Action of January 12, 2006, WO 02066484 discloses compounds wherein X is N and CH<sub>2</sub>. See pages 75-76, Tables 2B and 2C and pages 80-81, Table 3B and 3C.

Applicants' attorney respectfully request that a timely Notice of Allowance of claims 1-2, 4-6, 9-10, 14 and 17-18.

Respectfully submitted,

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